REMARKS

In the Office Action dated February 26, 2003, claims 1-7 were examined with the result that all claims were rejected. The Examiner made the rejection final. In response, Applicant has filed a Request for Continuing Examination, and has canceled claims 1-7 and added new claims 8-14. In view of the above amendments and following remarks, reconsideration of this application is requested.

In the Office Action, original claims 1-7 were rejected under 35 USC §103(a) as being unpatentable over DeLuca et al U.S. Patent 4,338,312 and DeLuca et al U.S. Patent 4,110,446. In response, Applicant has the following comments.

New claim 8 calls for a method of reducing the amount of phosphorus in cow manure by substituting a 1α-hydroxylated vitamin D compound for some or all of the inorganic phosphorus in the diet of a cow, and thereafter feeding the diet to the cow. The step of substituting a 1α-hydroxylated vitamin D compound for the inorganic phosphorus in a cow's diet distinguishes claim 8 from the prior art cited by the Examiner. Applicant believes the fact that new claim 8 calls for substituting a 1α-hydroxylated vitamin D compound for inorganic phosphorus in the diet of a cow cannot be found in the prior art, and distinguishes claim 1 from what is taught in the prior art.

U.S. Patent 4,338,312 cited by the Examiner relates to treatment of milk fever disease. There is no suggestion in the '312 patent of substituting a 1α-hydroxylated vitamin D compound for some or all of the inorganic phosphorus in the cow's diet and then feeding that diet to the cow on a daily basis. The entire disclosure of the '312 patent relates to a method for treating dairy cattle for parturient paresis which, by its very nature occurs at the time of parturition, i.e. in the cow's "dry period". Milk fever does not occur during a dairy cow's normal lactation period, and the disclosure of the '312 patent is thus inherently limited to treatments occurring in the dry period of dairy cows. Nevertheless, it is clear that the '312 reference does not teach, suggest or even mention the substitution of 1α-hydroxylated vitamin D compounds for inorganic phosphorus in the cow's diet.

The Examiner should note that columns 1 and 2 of the '312 reference provides a partial summary of current treatments for milk fever, and in each instance, the administration of the vitamin D compound is accomplished by injection shortly before parturition, i.e. typically 3-7 days before calving. The passage at column 2, lines 27-29 states:

> *"If the vitamin D dosage is given too far in advance the incidence of milk fever disease is actually increased by the treatment."*

The only conclusion that can be made from this statement is that a skilled person would readily recognize that giving a vitamin D compound to a dairy cow too far in advance of parturition would be ineffective and might be dangerous. The skilled person would infer that administering a vitamin D compound in the daily diet of a dairy cow would, in fact, increase the incidence of the disease, which is clearly an undesirable outcome. Thus, the '312 reference clearly teaches away from adding vitamin D compounds in the daily diet of a cow. Further, and more importantly, the '312 reference never teaches, suggests or infers in any way that the 1α-hydroxylated vitamin D compounds could be substituted for some or all of the inorganic phosphorus in the diet of a cow.

It is clear from the '312 reference that the description therein is directed to the administration of the vitamin D compound only at a time closely adjacent to parturition or calving, and only for a short period of time, preferably every five days, but not daily. Nowhere does the '312 reference teach or suggest that a vitamin D compound could be substituted for some or all of the inorganic phosphorus in the diet of the cow.

The same arguments referred to above can be made with respect to the '446 prior art reference cited by the Examiner. Nowhere does the '446 reference teach or suggest that 1α-hydroxyvitamin D compounds could be substituted for inorganic phosphorus in the diet of a cow.

As discussed in the introduction of the present patent application, much of the phosphorus in plant foods and feeds passes through the GI tract of the animal and is excreted in the animal's feces. In animal husbandry, this is accounted for in diet formulations by providing an inorganic phosphorus source in a feed supplement which is added to the normal diet to meet the animal's minimal phosphorus requirements. Since supplemental inorganic phosphorus is a relatively expensive ingredient in a dairy cow's diet, its reduction and/or elimination is desirable from a cost standpoint. However, in dairy cows, such a reduction of inorganic phosphorus cannot be made at the expense of milk yields. In the past, a skilled person would not have substituted a vitamin D compound for the phosphorus in a cow's diet because by doing so, one would not expect to meet the minimum phosphorus requirements of the animal. Thus, new claim 8 clearly goes against the common teaching in the prior art.

The data in the present patent application demonstrates unexpected results over the prior art. A skilled person would clearly not feed a diet to an animal which would not meet that animal's minimum phosphorus requirements. Otherwise, the diet would be assumed to be insufficient to provide adequate nutrition for the animal. Therefore, there is no motivation for a skilled person to substitute a 1α-hydroxylated vitamin D compound for some or all of the inorganic phosphorus in the diet of a cow. However, the data in the application as filed clearly show that, according to the present invention, although the diet contains low levels of phosphorus, milk production is maintained. To a skilled person, this is an unexpected result since it was normally assumed in the past that one needed to feed supplemental inorganic phosphorus to a cow to maintain its milk production. The substitution of a vitamin D compound for some or all of the inorganic phosphorus, and the subsequent maintenance of milk production, is an entirely unexpected result which would not have been predicted by a skilled person in light of the available prior art.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By _____
Joseph D. Kuborn
Reg. No. 40,689
(414) 271-7590

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202